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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/196,867	11/20/98	KELSALL B	14014.0312

HM22/0703

MARY L MILLER
NEEDLE & ROSENBERG
SUITE 1200 THE CANDLER BULDG
127 PEACHTREE STREET N E
ATLANTA GA 30303-1811

EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	11

DATE MAILED: 07/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/196,867	Kelsall et al
Examiner	**Group Art Unit**
D Cloux, Amy	1644

☒ Responsive to communication(s) filed on *mailed on 4-20--00*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-8 and 10* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8 and 10* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment, mailed 4-20-200 (Paper No. 10), is acknowledged. Claims 1-8, and 10 are pending and being examined presently.

2. In view of applicant's arguments and amendments to the instant claims, only the 102(a) and 103 art rejections are maintained.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-2 are rejected under 35 U.S.C. § 102(a) as being anticipated by Marth et al. (J. Exp. Med. 185:1987-1995, June 2, 1997).

Applicants arguments have been considered but are not deemed persuasive.

Applicants assert that the 102(a) rejection is improper because the authors of the referenced teachings are both named inventors in the present application. However the authorship of the referenced teachings is only Marth and Kelsall, while the

inventorship includes Strobber and Fuss as well as Marth and Kelsall.

Marth et al teach a method of suppressing IL-12 production and it's associated inflammatory response (as shown by the suppression of IFN-gamma production) in a murine model of septic shock by treatment with CR3 antibodies (see entire article, especially Figure 7). Therefore, the referenced teachings anticipate the claimed invention.

Therefore the rejection is proper and is maintained for the reasons of record.

6. Claims 1-8 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Marth et al. (J. Exp. Med. 185:1987-1995, June 2, 1997) in view of Neurath et al (J. Exp. Med. 182:1281-1290, 1995) and Duchmann et al. (Eur. J. Immunol. 26:934-938, 1996).

Applicants arguments have been considered but are not deemed persuasive.

Applicants assert that the 103(a) rejection is improper because the referenced teaching is not a reference "by others" in the present application. However, as stated above, the authorship of the referenced teachings is only Marth and Kelsall, while the inventorship includes Strobber and Fuss as well as Marth and Kelsall, and therefore is a reference by others.

Marth et al. teach as described above, and also teach the ability of antibodies to CR3 to ameliorate Th1 cell mediated autoimmune diseases (see entire article, especially page 1993, column 2, first paragraph). However, Marth et al do not specifically teach a method of reducing the symptoms of autoimmune diseases such as the inflammatory bowel disease of Crohn's disease in humans using ligands to CR-3 such as antibodies to CR-3.

Neurath et al. teaches the method of administration of antibodies against IL-12 which resulted in the abrogation of the colitis induced by TNBS in a murine model of chronic intestinal inflammation with symptoms including weight loss, and mimics some characteristics of Crohn's disease in humans (see entire article, especially the abstract,) and that the inflammation induced by TNBS is associated with a TH-1 response and can be abrogated by systemic treatment with antibodies against IL-12 (see entire article, especially page 1288). Neurath et al. also teaches that IL-12 has pleiotropic effects, plays a pivotal role in driving the TH 1 response and can be efficiently induced by bacteria and bacterial products (see entire article, especially page 1281, columns 1 and 2).

Duchmann et al teach that the pathogenesis of inflammatory bowel disease is due to the hyperresponsiveness to intestinal flora (See entire article, especially the abstract and page 934, column 2).

Therefore, one of ordinary skill in the art at the time the invention was made, who wanted to treat the symptoms of an autoimmune inflammatory disease such as Crohn's disease, would have been motivated to substitute the anti-CR3 antibodies as taught by Marth et al. for the antibodies against IL-12, in a method to down regulate IL-12 production in order to reduce an IL-12 inflammatory response and to abrogate the IL-12 mediated symptoms of an autoimmune disease such as inflammatory bowel disease taught by Neurath et al, especially given the success of anti-CR3 antibodies in down regulating IL-12 and its associated inflammation in an animal model of septic shock as taught by Marth et al, because the anti-CR3 antibodies down regulate IL-12 at its source in a more specific manner than anti- IL-12 antibodies. Since the pathogenesis of autoimmune inflammatory disease may be a result of hyperresponsiveness to intestinal flora taught by Duchmann, this increased specificity of anti-CR3 antibodies relative to anti-IL-12 antibodies is due to the ability of the anti-CR3 antibodies to abrogate the initial response derived from CR-3 recognition of bacterial substances by phagocytes, and stem the resulting secretion of IL-12 at its cellular source, rather than to sequester the IL-12 once it has been produced.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Therefore the rejection is proper and is maintained for the reasons of record.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640, Technology Center 1600
June 30, 2000

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644